DOCKET NO.: NIHA-0278 Application No.: 10/578,385 Office Action Dated: February 12, 2010

REMARKS

Claims 1-13, 15-41, 43-50 and 52-76 are currently pending and are subject to a restriction requirement as set forth in the Office Action dated February 12, 2010. Claims 14, 42, 51 and 77-79 were previously cancelled.

The Office has restricted the claim groups as follows:

Group I: Claims 1-13, 15-41, which are drawn to a method of preparing an antigen-nanoparticle conjugate and an an antigen-nanoparticle conjugate comprising a plurality fo carbohydrate antigens conjugated to a nanoparticle; and

Group II: Claims 43-50 and 52-76, which are drawn to a method for inhibiting metastasis of carcinoma cells comprising administering an antigen-nanoparticle conjugate.

The Office alleges that Groups I and II are not so linked to as to form a single general inventive concept under PCT Rule 13.1.

Legal Standard

According to MPEP § 803, there are two criteria for a proper requirement for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05-§ 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

For purposes of the initial requirement, a serious burden may be *prima facie* shown if the examiner shows separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02. Applicants respectfully submit that the examiner has not shown any of these requirements. In the subject application, the claims have been restricted but all share the same novel features of:

a plurality of carbohydrate antigens being conjugated to a nanoparticle, wherein the carbohydrate antigens include TF antigen, T_n antigen, Gb1 antigen, GM1 antigen, GM3 antigen, Lewis Y Antigen, or any combination thereof

Applicants submit that it is relatively straightforward to conduct a search limited to the aforementioned novel features. Searching for any of the recited antigens with the term

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"nanoparticle" should capture all of the relevant prior art, whether drawn to the composition, the method of making the composition, or the method for inhibiting metastasis of carcinoma cells in a mammal. Thus, applicants submit that a restriction is not proper.

While applicants do not necessarily agree with the Office, applicants elect with traverse to prosecute the claims of Group II. Applicants request the Office to reconsider rejoinder of the Group I claims, as their examination, together with the claims of Group II, would not be unduly burdensome as stated above.

Nevertheless, claims 1-13 and 15-41 have been withdrawn without prejudice subject to the restriction requirement. No new matter is entered upon entry of these amendments. Applicants reserve the right to file one or more continuation or divisional patent applications to the unelected claims.

Applicants request the Examiner to examine these claims at her earliest convenience.

In summary, Applicants request reconsideration of the restriction requirement. If the

Examiner is of a contrary view or wishes to further discuss the merits of the application, the Examiner is requested to contact the undersigned attorney at (215) 564-8969.

The Commissioner is hereby authorized to charge any fee deficiency, charge any additional fees, or credit any overpayment of fees, associated with this application in connection with this filing, or any future filing, submitted to the U.S. Patent and Trademark Office during the pendency of this application, to Deposit Account No. 23-3050.

Date: May 7, 2010 /Jeffrey H. Rosedale/ Jeffrey H. Rosedale

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